UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/649,990	08/27/2003	Murty Mangena		6744

7590 08/28/2007

Dr. Murty Mangena
518 Codell Drive
Lexington, KY 40509

EXAMINER
FUBARA, BLESSING M

ART UNIT	PAPER NUMBER
1618	

MAIL DATE	DELIVERY MODE
08/28/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/649,990	MANGENA ET AL.	
	Examiner	Art Unit	
	Blessing M. Fubara	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 April 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-8 and 10-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8 and 10-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *4/17/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Examiner acknowledges receipt of properly executed declaration, IDS, amendment to the specification and claims, and remarks, all filed 4/17/07.

Previous rejections that are not reiterated herein are withdrawn.

Information Disclosure Statement

1. The information disclosure statement filed 4/17/07 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited foreign patent document; each non-patent literature publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered.

Further, it is brought to applicant's attention that page 1 of the document titled "information disclosure have as the serial number 10/646,990 instead of 649,990. Correction is respectfully requested.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

4. Claims 1-8 and 10-20 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Lawter et al. (US 5,000,886) in view of Oshlack et al. (US 6,716,449) or Hille et al. (JP 403103732A).

Lawter prepares microcapsules of pharmaceutical agents in the presence of halogenated organic solvent such as methylene chloride (column 5, lines 20-27), phosphate buffer, PLGA having viscosity in one example being 0.65 dl/g (Example 4) and viscosity in another example being 0.29 dl/g (Example 5). Lawter contemplates preparing many pharmaceutical agents including buprenorphine (column 4, lines 10-40 with specific emphasis on line 37 for the buprenorphine). While the embodiments exemplified do not contain buprenorphine, it is noted that any of the drugs listed in the column 3, line 48 to column 4 line 40 can be prepared administered by the process of Lawter.

It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose....[T]he idea of combining them flows logically from their having been

individually taught in the prior art." In re Kerkhoven, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980).

In this case, a third composition that contains PLGA having different viscosities and containing buprenorphine is rendered obvious with expectation of success that the compositions can be successfully formulated.

Lawter contemplates administering the formulation to a subject by any means or route (column 5, lines 56 and 57) and administering a buprenorphine formulation to a subject would mean that the individual is identified as needing treatment with buprenorphine and thus the method of claim 20 is met.

Lawter's buprenorphine formulation does not contain polyvinyl alcohol. However, buprenorphine is known in the art to be formulated with polyvinyl alcohol as is disclosed by Oshlack in example 20 and as disclosed in the English abstract of Hille (JP403193732A). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to formulate the buprenorphine formulation according to Lawter and include PVA as suggested by Oshlack or Hille.

Response to Arguments

5. Applicant's arguments filed 4/17/07 have been fully considered but they are not persuasive.

Applicant argues that a) buprenorphine is one of a long list of active agents, and because the pharmaceutical art is unpredictable (quoting examiner), one cannot pick and chose the elements of Lawter to arrive at the claimed invention so that making a third composition from two examples that teach different viscosities flies in the face of the unpredictable

nature of the pharmaceutical art, b) "Lawter teaches away from the claimed invention by describing the use of one PLGA having one viscosity and not a mixture of different materials," c) Oshlack does not overcome the deficiencies of Lawter because Example 20 of Oshlack is prophetic and no viscosity is specified, d) Hille describes buprenorphine transdermal patch and mentions PVA among other materials.

Response:

Lawter is concerned with preparing microcapsules in which any of the drugs listed is combined with polymers such as polyglycolide, polylactide, poly(glycolide-co-lactide) or blends thereof (column 3, line 50 to column 4 line 60). Regarding a), any of the drugs can be formulated according to the process of Lawter and buprenorphine is specifically named as one of the drugs to be formulated. Regarding b), Lawter does not teach away form the invention because Lawter specifically teaches that blends of polymers can be used (column 4, lines 59 and 60). Regarding c), while applicant refers to example 20 of Oshlack as prophetic, the example teaches combining buprenorphine, poly(lactide-co-glycolide) and polyvinyl alcohol and Oshlack is relied upon for teaching formulating buprenorphine with polyvinyl alcohol and also for d), Hille is relied upon teaching formulating buprenorphine with polyvinyl alcohol. Therefore, one would arrive at the claimed invention by using the teaching of Lawter that blends of polymers can be used when formulating active agents such as buprenorphine and the examples guides the artisan to use specific PLGA's having the specific viscosities.

6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Blessing M. Fubara whose telephone number is (571) 272-0594. The examiner can normally be reached on 7 a.m. to 5:30 p.m. (Monday to Thursday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Blessing Fubara
Patent Examiner
Tech. Center 1600

MICHAEL G. HARTLEY
SUPERVISORY PATENT EXAMINER